

# **PUMP CASSETTE AND METHODS FOR USE IN MEDICAL TREATMENT SYSTEM USING A PLURALITY OF FLUID LINES**

## **RELATED APPLICATIONS**

**[0001]** This application is a continuation of U.S. patent application Ser. No. 16/391,104, filed Apr. 22, 2019, which is a division of U.S. patent application Ser. No. 15/174,969, filed Jun. 6, 2016 and issued as U.S. Pat. No. 10,265,451 on Apr. 23, 2019, which is a division of U.S. patent application Ser. No. 12/864,378, filed Dec. 9, 2010 and issued as U.S. Pat. No. 9,358,332 on Jun. 7, 2016, which is a National Stage of International Patent Application No. PCT/US2009/000436, filed Jan. 23, 2009, which claims priority under 35 U.S.C. § 119(e) to U.S. Provisional Patent Application No. 61/011,967, filed Jan. 23, 2008, and U.S. Provisional Patent Application No. 61/058,469, filed Jun. 3, 2008, and entitled. Each of the above-indicated applications is incorporated herein by reference in its entirety.

## **BACKGROUND**

**[0002]** Peritoneal Dialysis (PD) involves the periodic infusion of sterile aqueous solution (called peritoneal dialysis solution, or dialysate) into the peritoneal cavity of a patient. Diffusion and osmosis exchanges take place between the solution and the bloodstream across the natural body membranes. These exchanges transfer waste products to the dialysate that the kidneys normally excrete. The waste products typically consist of solutes like sodium and chloride ions, and other compounds normally excreted through the kidneys like urea, creatinine, and water. The diffusion of water across the peritoneal membrane during dialysis is called ultrafiltration.

**[0003]** Conventional peritoneal dialysis solutions include dextrose in concentrations sufficient to generate the necessary osmotic pressure to remove water from the patient through ultrafiltration.

**[0004]** Continuous Ambulatory Peritoneal Dialysis (CAPD) is a popular form of PD. A patient performs CAPD manually about four times a day. During a drain/fill procedure for CAPD, the patient initially drains spent peritoneal dialysis solution from his/her peritoneal cavity, and then infuses fresh peritoneal dialysis solution into his/her peritoneal cavity. This drain and fill procedure usually takes about 1 hour.

**[0005]** Automated Peritoneal Dialysis (APD) is another popular form of PD. APD uses a machine, called a cycler, to automatically infuse, dwell, and drain peritoneal dialysis solution to and from the patient's peritoneal cavity. APD is particularly attractive to a PD patient, because it can be performed at night while the patient is asleep. This frees the patient from the day-to-day demands of CAPD during his/her waking and working hours.

**[0006]** The APD sequence typically lasts for several hours. It often begins with an initial drain phase to empty the peritoneal cavity of spent dialysate. The APD sequence then proceeds through a succession of fill, dwell, and drain phases that follow one after the other. Each fill/dwell/drain sequence is called a cycle.

**[0007]** During the fill phase, the cycler transfers a predetermined volume of fresh, warmed dialysate into the peritoneal cavity of the patient. The dialysate remains (or "dwells") within the peritoneal cavity for a period of time.

This is called the dwell phase. During the drain phase, the cycler removes the spent dialysate from the peritoneal cavity.

**[0008]** The number of fill/dwell/drain cycles that are required during a given APD session depends upon the total volume of dialysate prescribed for the patient's APD regimen, and is either entered as part of the treatment prescription or calculated by the cycler. APD can be and is practiced in different ways.

**[0009]** Continuous Cycling Peritoneal Dialysis (CCPD) is one commonly used APD modality. During each fill/dwell/drain phase of CCPD, the cycler infuses a prescribed volume of dialysate. After a prescribed dwell period, the cycler completely drains this liquid volume from the patient, leaving the peritoneal cavity empty, or "dry." Typically, CCPD employs 4-8 fill/dwell/drain cycles to achieve a prescribed therapy volume.

**[0010]** After the last prescribed fill/dwell/drain cycle in CCPD, the cycler infuses a final fill volume. The final fill volume dwells in the patient for an extended period of time. It is drained either at the onset of the next CCPD session in the evening, or during a mid-day exchange. The final fill volume can contain a different concentration of dextrose than the fill volume of the successive CCPD fill/dwell/drain fill cycles the cycler provides.

**[0011]** Intermittent Peritoneal Dialysis (IPD) is another APD modality. IPD is typically used in acute situations, when a patient suddenly enters dialysis therapy. IPD can also be used when a patient requires PD, but cannot undertake the responsibilities of CAPD or otherwise do it at home.

**[0012]** Like CCPD, IPD involves a series of fill/dwell/drain cycles. Unlike CCPD, IPD does not include a final fill phase. In IPD, the patient's peritoneal cavity is left free of dialysate (or "dry") in between APD therapy sessions.

**[0013]** Tidal Peritoneal Dialysis (TPD) is another APD modality. Like CCPD, TPD includes a series of fill/dwell/drain cycles. Unlike CCPD, TPD does not completely drain dialysate from the peritoneal cavity during each drain phase. Instead, TPD establishes a base volume during the first fill phase and drains only a portion of this volume during the first drain phase. Subsequent fill/dwell/drain cycles infuse and then drain a replacement volume on top of the base volume. The last drain phase removes all dialysate from the peritoneal cavity.

**[0014]** There is a variation of TPD that includes cycles during which the patient is completely drained and infused with a new full base volume of dialysis.

**[0015]** TPD can include a final fill cycle, like CCPD. Alternatively, TPD can avoid the final fill cycle, like IPD.

**[0016]** APD offers flexibility and quality of life enhancements to a person requiring dialysis. APD can free the patient from the fatigue and inconvenience that the day to day practice of CAPD represents to some individuals. APD can give back to the patient his or her waking and working hours free of the need to conduct dialysis exchanges.

**[0017]** Still, the complexity and size of past machines and associated disposables for various APD modalities have dampened widespread patient acceptance of APD as an alternative to manual peritoneal dialysis methods.

## **SUMMARY OF INVENTION**

**[0018]** Aspects of the invention relate to various components, systems and methods for use in medical applications, including medical infusion operations such as peritoneal